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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,214	02/22/2002	Roger D.A. Lipman	47915/KMO	1358

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,214	LIPMAN, ROGER D.A.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment, filed 01/20/2004.

Claims 1-5 and 7-16 are included in the prosecution.

Claim Rejections - 35 USC § 103

1. Claims 1-5 and 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,231,369 ('369) in view of US 5,817,332 ('332).

US '369 teaches an adhesive sealing material for use in connection to ostomy devices composed of continuous rubber phase and hydrocolloid dispersed in the continuous phase, i.e. forming discontinuous phase (abstract; col.4, lines 30-31, 55-60). The rubber phase is made of styrene copolymer and polyisobutylene wherein the styrene copolymer forms 40 wt % or below of the of the rubber (col.5, lines 8-10, 36-37, 46). Example O, Table III, shows that the styrene copolymer "Cariflex" forms 10.9% of the composition, and polyisobutylene forms 18.1 % of the composition. The hydrocolloid is a mixture of more than one hydrocolloid in an amount ranges from 48-56 % (col.8, lines 52-54). The composition further comprises oils, medicaments, or bactericides (col.6, lines 33, 45-47). The composition is supplied by release liner, i.e. substrate (col.9, lines 1-2).

The reference does not list cyclodextrin among the hydrocolloids, or the material of the backing.

The non-adhesive water proof backing are well known in the art, and are widely used for wound dressings and transdermal drug delivery devices.

US '332 teaches a transdermal device for the delivery of therapeutic agent comprises the drug complexed with cyclodextrin to enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin (abstract; col.2, lines 52-56, 63-64; col.4, lines 37-39). The device comprises the cyclodextrin drug complex forming plurality of cores dispersed in a polymer matrix and a backing layer (col.3, lines 50-53, 60; col.5, lines 21-30). The drug includes antibacterial agents (col.5, line 5).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a composition comprising continuous rubbery phase and discontinuous hydrocolloid phase as disclosed by US '369, and replace the hydrocolloid by cyclodextrin complexed with drugs as disclosed by US '332, motivated by the teaching of US '332 that drugs complexed with cyclodextrin enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin, with reasonable expectation of having a composition comprising rubbery continuous phase and cyclodextrin discontinuous phase that release drug from the devices containing the composition at steady controlled rate with success.

2. Claims 1-5 and 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,367,732 ('732) in view of US '332.

US '732 teaches a skin barrier comprises an adhesive layer comprising discontinuous hydrocolloid phase dispersed in a continuous phase comprising styrene copolymers and polyisobutylene (abstract; col.5, lines 24-26, 49; col.6, lines 35-36; col.8, lines 31-42, 62-64). The adhesive composition further comprises bacteriostatic or fungicidal agents (col.6, line 59). The hydrocolloid phase comprises at least one hydrocolloid, and forms 10-55% of the composition of the adhesive layer (col.8, lines 53-55; col.9, lines 22-23). The styrene copolymer forms 10-40% of the continuous phase (col.9, line 16). The skin barrier further comprises a non-adhesive, water impervious film secured to the adhesive layer (col.3, lines 54-56).

The reference does not list cyclodextrin among the hydrocolloids.

US '332 teaches a transdermal device for the delivery of therapeutic agent comprises the drug complexed with cyclodextrin to enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin (abstract; col.2, lines 52-56, 63-64; col.4, lines 37-39). The device comprises the cyclodextrin drug complex forming plurality of cores dispersed in a polymer matrix and a backing layer (col.3, lines 50-53, 60; col.5, lines 21-30). The drug includes antibacterial agents (col.5, line 5).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a composition comprising continuous rubbery phase

and discontinuous hydrocolloid phase as disclosed by US '732, and replace the hydrocolloid by cyclodextrin complexed with drugs as disclosed by US '332, motivated by the teaching of US '332 that drugs complexed with cyclodextrin enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin, with reasonable expectation of having a composition comprising rubbery continuous phase and cyclodextrin discontinuous phase that release drug from the devices containing the composition at steady controlled rate with success.

3. Claims 1-5 and 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/14282 ('282) in view of US '332.

WO '282 teaches a pressure sensitive adhesive material comprising continuous phase of rubber comprising styrene copolymer and polyisobutylene; and a discontinuous phase comprising hydrocolloid (abstract). The discontinuous phase forms 15-70 wt % of the composition (page 11, first paragraph). The styrene copolymer forms 10-30 wt % of the composition, and the polyisobutylene forms 20-60 wt % of the composition (page 15, claims 1-4). Example 2, page 13, shows that the composition comprising more than one hydrocolloid. The composition comprises bactericides (page 11, third paragraph). The adhesive composition is coated on non-adhesive waterproof film and used in adhesive barrier or dressing for medical use (page 16, claim 13).

The reference does not list cyclodextrin among the hydrocolloids.

US '332 teaches a transdermal device for the delivery of therapeutic agent comprises the drug complexed with cyclodextrin to enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin (abstract; col.2, lines 52-56, 63-64; col.4, lines 37-39). The device comprises the cyclodextrin drug complex forming plurality of cores dispersed in a polymer matrix and a backing layer (col.3, lines 50-53, 60; col.5, lines 21-30). The drug includes antibacterial agents (col.5, line 5).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a composition comprising continuous rubbery phase and discontinuous hydrocolloid phase as disclosed by WO '282, and replace the hydrocolloid by cyclodextrin complexed with drugs as disclosed by US '332, motivated by the teaching of US '332 that drugs complexed with cyclodextrin enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin, with reasonable expectation of having a composition comprising rubbery continuous phase and cyclodextrin discontinuous phase that release drug from the devices containing the composition at steady controlled rate with success.

Response to Arguments

4. Applicant's arguments filed 01/20/2004 have been fully considered but they are not persuasive. Applicant traverse the above rejection by arguing that US '369, US '732 and WO '282 do not teach cyclodextrin, and US '332 does not teach cyclodextrin having

an odor absorbing properties. One skilled in the art seeking to improve the odor-absorbency of the sealing materials disclosed in U.S. '369 would not consider the disclosure of U.S. '332, which does not address the problem of odor-absorbency. It cannot, therefore, be concluded that it would be in any way obvious to combine these two references, since neither reference addresses the question of odor- absorbency, and it would not be obvious from either reference that a combination of cyclodextrin with another hydrocolloid would have enhanced odor-absorbing properties.

In response to the above argument, the examiner position is that the claims are directed to composition, and all the elements of the composition are taught by the combined teaching of the reference. The intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.
In response to applicant's argument that it would not be obvious from either reference that a combination of cyclodextrin with another hydrocolloid would have enhanced odor-absorbing properties, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the

invention to deliver a composition comprising continuous rubbery phase and discontinuous hydrocolloid phase as disclosed by US '369, and replace the hydrocolloid by cyclodextrin complexed with drugs as disclosed by US '332, motivated by the teaching of US '332 that drugs complexed with cyclodextrin enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin, with reasonable expectation of having a composition comprising rubbery continuous phase and cyclodextrin discontinuous phase that release drug from the devices containing the composition at steady controlled rate with success.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., enhancing odor-absorbing properties) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that the present invention combines cyclodextrin and another hydrocolloid to enhance odor absorption properties, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Further, one cannot show nonobviousness by attacking the references individually where the rejections are based on combination of references. *See In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). All the primary references teach the combination of hydrocolloids, and the secondary reference teaches cyclodextrin for transdermal application, thus, the combination is reasonable. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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